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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,972	03/07/2005	Axel Brättstrom	26638U	7955

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112 South West Street  
Alexandria, VA 22314

EXAMINER
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CLARK, AMY LYNN

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/526,972

Applicant(s)

BRATTSTROM, AXEL

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on 15 September 2006 with the amendment of claims 1-4 and 9, the cancellation of claims 5-8 and the addition of newly submitted claims 10-15.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 and 9-15 are currently pending

Claims 1-4 and 10-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

**Claim 9 is currently under examination.**

### ***Election/Restrictions***

Newly submitted claims 1-4 and 10-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original invention was drawn to a method of producing a vegetal plant extract. Newly amended claims 1-4 are amended in such a way that they present completely new claims wherein the claims are now drawn to a method of using a medicament. Newly added claims 10-15 are also drawn to a method of using a medicament.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-4 and 10-15

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withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 15 September 2006, with respect to the rejection of Claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Kreuter et al. (A\*), have been fully considered and are persuasive in view of newly amended claim 1.

Newly amended Claim 9 remain rejected under 35 U.S.C. 102(a) as being anticipated by Houston et al. (B\*).

Houston teaches a pharmaceutical composition (which reads on medicament) comprising of an extract of black cohosh (See page 3, paragraph 0031), which is synonymous with *Cimicifuga racemosa*, and polyvinylpyrrolidone (See page 7, paragraph 0083). Houston further teaches that black cohosh contains isoflavones, which are used to treat hot flashes in post-menopausal women (See page 1, paragraph 0009, continued onto page 2). Houston does not expressly teach that the composition is capable of being used as a substitute for or a complement to hormone replacement therapy, however the composition as taught by Houston is one in the same as that claimed by Applicant, therefore, the properties of the composition (as a substitute for or a complement to hormone replacement therapy), as claimed by Applicant, are inherent to the composition taught by Houston. Although Houston does not expressly teach an extract

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obtained by concentration of an extract fluid from *Cimicifuga racemosa* in the presence of an effective amount of poly(vinylpyrrolidone) as a solvent mediator, it should be noted that Claim 9 constitutes a Product-by-Process type claim. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, the reference anticipates the claimed subject matter.

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This rejection is maintained for reasons of record set forth in the paper mailed on 28 February 2006 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 15 September 2006.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues the teachings of Houston do not teach the claimed elements in the order presented in claim 9, wherein claim 9 is directed to a medicament capable of substituting or complementing hormone replacement therapy, wherein the medicament consists of an extract obtained in concentration of an extract fluid from *Cimicifuga racemosa* in the present an effective amount of poly(vinylpyrrolidone). Applicant further argues that in contrast, Houston teaches that enzymes mixed with poly(vinylpyrrolidone) may be concomitantly administered with *Cimicifuga racemosa* and that the reference does not teach a composition obtained by the extraction and concentration process of claim 9, which requires that concentration take place in the presence of poly(vinylpyrrolidone).

However, this argument is not found persuasive because Houston teaches a pharmaceutical composition (which reads on medicament) comprising of an extract of black cohosh, which is synonymous with *Cimicifuga racemosa*, and polyvinylpyrrolidone, that black cohosh contains isoflavones, which are used to treat hot flashes in post-menopausal women. It is noted that Houston does not expressly teach that the composition is capable of being used as a substitute for

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or a compliment to hormone replacement therapy, however the composition as taught by Houston is one in the same as that claimed by Applicant, therefore, the properties of the composition (as a substitute for or a compliment to hormone replacement therapy), as claimed by Applicant, are inherent to the composition taught by Houston. Furthermore, although Houston does not expressly teach an extract obtained by concentration of an extract fluid from *Cimicifuga racemosa* in the presence of an effective amount of poly(vinylpyrrolidone) as a solvent mediator, it should be noted that Claim 9 constitutes a Product-by-Process type claim. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the

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claimed composition and the composition of the prior art. See *In re Best*, 562

F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, the reference anticipates the claimed subject matter.

**No claims are allowed.**

### ***Conclusion***

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark  
AU 1655

Amy L. Clark  
November 20, 2006

  
MICHELE FLOOD  
PRIMARY EXAMINER